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EXAMINER

SOUAYA, JEHANNE E

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/898,200

Applicant(s)

COHN ET AL.

Examiner

Jehanne E Souaya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 109-113, 115, 117-120 and 151-153 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 109-113, 115, 117-120 and 151-153 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: "notice to comply", CRF Problem Report.

DETAILED ACTION

Election/Restrictions

1. Applicants' election of group I, claims 109-113, 115, 117-120 and 151-153, without traverse, in the response dated June 6, 2003 is acknowledged. Claims 109-113, 115, 117-120 and 151-153 are pending in the instant application. An action on the merits is set forth below.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see p. 40 for example). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Sequence Listing

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached CRF Diskette Problem Report. A complete reply to this office action must include a response to the "Notice to Comply".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 109-113, 115, 117-120 and 151-153 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to nucleic acid sequences, primer pairs, and kits comprising such. The recitation of nucleic acid sequences “comprising”, sequences “complementary”, “gene specific fragments”, and “PAPSS2 specific nucleic acids” encompasses an extremely large number of genomic sequences, mutants, variants, and homologs of human PAPSS2 which have not been taught or described in the specification. The specification teaches the sequence of SEQ ID NO 1, which is the sequence of human PAPSS2. The claims, however, only recite sequences from within SEQ ID NO: 1, wherein sequences “comprising”, “complementary”, “gene specific fragments” and PAPSS2 specific fragments of this minimal recitation of contiguous nucleotides within SEQ ID NO 1 or SEQ ID NOS 3-6, 11-18 and 28 encompass genomic sequences, as well as mutants, variants and homologs of human PAPSS2 which have not been taught or described by the specification. The specification does not define the term “PAPSS2” such that the skilled artisan would be able to determine what constitutes a PAPSS2 specific nucleic acid. Further, the specification does not define the term “complimentary”. As such, the term has been broadly interpreted to encompass sequences which need only have some degree of complementarity to the recited sequences. These recitations, along with the terms “comprising” and “gene specific fragments” encompass a large genus of nucleic acids. However, the disclosure of the human and

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mouse PAPSS2 cDNA represent a species of this extremely large genus of nucleic acids and is not representative of this large genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOS: 1, 3-6, 11-18, and 28, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993), and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it

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obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 109-113 and 115 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5,474,796; 12/1996).

The claims are drawn to nucleotide sequences complimentary to, SEQ ID NO: 1 or degenerate coding sequences thereof, or gene specific fragments, or sequences that minimally contain 5 contiguous sequences of SEQ ID NOS: 3-6. As the claims do not recite any upper length limitations and do not define the terms "gene specific fragment" or PAPSS2 specific nucleotide sequence, the claims encompass a large number of possible 10 mer nucleic acid sequences. Brennan teaches making every possible 10 nucleic acid sequence (see example 4, col. 9), many of which are encompassed by the instant claims.

8. Claims 109-113, 115, and 117-120 are rejected under 35 U.S.C. 102(a) as being anticipated by Haque M.F. et al (hereinafter referred to as Haque; Nature Genetics, vol. 20, October 1998).

Haque teaches primer sequences (see p. 161, col 2: "Radiation hybrid mapping" and "Mutation analysis") which are identical to SEQ ID NOS: 3-6, and anticipate limitations in each of the claims.

9. Claims 109-113, 115 and 117-120 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurima et al (hereinafter referred to as Kurima; PNAS, vol. 95, pp 8681-8685, July 1998).

Kurima teach the nucleotide sequence of murine SK2, which is 85.6% identical to SEQ ID NO: 1 over nucleotides 92-1924 (see attached sequence alignment). As the claims do not recite an upper or lower length limitation or define 1) the degree of complementarity to SEQ ID NO: 1, 2) what a gene specific fragment of SEQ ID NO: 1 encompasses, or 3) what constitutes a PAPSS2 specific nucleic acid sequence, the nucleotide sequence of murine SK2 anticipates the nucleic acids of claims 109-113 and 115. Further, Kurima teaches nucleic acid primers for amplification (see p. 8682, 2nd col. First full para) which contain sequences complimentary (albeit not the full complement) to the claimed nucleic acids. Such sequences have been broadly interpreted to encompass "gene specific fragments" and "PAPSS2 specific nucleic acid sequences".

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10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 151-153 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haque or in the alternative, Kurima, each in view of Ahern (The Scientist, vol. 9, 1995, pages 1-5 from the internet).

Haque teaches primer sequences (see p. 161, col 2: "Radiation hybrid mapping" and "Mutation analysis") which are identical to SEQ ID NOS: 3-6.

Kurima teaches the nucleotide sequence of murine SK2, which is 85.6% identical to SEQ ID NO: 1 over nucleotides 92-1924 (see attached sequence alignment). As the claims do not recite an upper or lower length limitation or define 1) the degree of complementarity to SEQ ID NO: 1, 2) what a gene specific fragment of SEQ ID NO: 1 encompasses, or 3) what constitutes a PAPSS2 specific nucleic acid sequence, the nucleotide sequence of murine SK2 are encompassed by the claimed nucleic acids of claims 109-113 and 115. Further, Kurima teaches nucleic acid primers for amplification (see p. 8682, 2nd col. First full para) which contain sequences complimentary (albeit not the full complement) to the claimed nucleic acids. Such sequences have been broadly interpreted to encompass "gene specific fragments" and "PAPSS2 specific nucleic acid sequences".

Neither Haque nor Kurima teach the primer pairs in kit format, however Ahern teaches that packaging biochemical reagents in kit format save the researcher time and provides convenience (see p. 4, para 1-2). Therefore, it would have been prima facie obvious to one of

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ordinary skill in the art at the time the invention was made to package the primer pairs of either Haque or Kurima in kit format, as taught by Ahern, for the purpose of making the methods of Haque or Kurima easier and more convenient to perform. The ordinary artisan would have been motivated to package the primer pairs in kit format as Ahern teaches that packaging reagents in kit format offer scientists the opportunity to better manage their time.

Applicant should note that the instructions for use in the kit carry no patentable weight.

Conclusion

12. No claims are allowable.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Primary Examiner
Art Unit 1634

9/5/03